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K023272
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# SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.92.

## A. Submitter's Name, Address, Phone and Fax Number

| | |
|---|---|
| 1. Applicant: | Olympus Optical Co., Ltd.<br>2-3-1 Shinjuku Monolis Nishi-shinjuku<br>Shinjuku-ku, Tokyo, Japan, 163-0914 |
| Registration No. | 8010047 |
| Address, Phone and Fax Numbers of R&D Department Endoscope Division: | 2951 Ishikawa-Cho,<br>Hachioji-shi, Tokyo 192-8507 Japan<br>Tel. 426-42-2891<br>Fax 426-42-2291 |
| 2. Initial Importer | Olympus America Inc.<br>Two Corporate Center Drive<br>Melville, NY 11747-3157 |
| Registration No. | 2429304 |
| 3. Contact Person | Laura Storms-Tyler<br>Director, Regulatory Affairs<br>Olympus America Inc.<br>Two Corporate Center Drive<br>Melville, NY 11747-3157<br>Tel (631)-844-5688<br>Fax (631)-844-5416 |

## B. Device Name, Common Name

1. Trade/Proprietary Name and Common Name
   Trade Name: DISPOSABLE ASPIRATION NEEDLE NA-200H
   Common Name: ASPIRATION NEEDLE

2. Class, Classification Number and Classification Name

| Classification Number | Classification Name | Class |
|---|---|---|
| 21 CFR 876.1075 | Gastroenterology-urology biopsy instrument | II |

3. Identification of Legally Marketed Devices Which We Claim Substantial Equivalence

| Description | Model No | Manufacturer | #K |
|---|---|---|---|
| ASPIRATION NEEDLE | NA-10J-1 | Olympus Optical Co., Ltd. | K973128 |
| VACLOK Syringe | - | Merit Medical System Inc. | K994253 |
| STOPCOCK(One-port manifold) | - | Merit Medical System Inc. | K934123 |

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## C. Description of the Device(s)

**NA-200H**

DISPOSABLE ASPIRATION NEEDLE NA-200H is a modified version of NA-10J-1 Aspiration Needle, which was cleared #K973128. When compared with the predicate device, the following modifications have been made to the NA-10J-1 needle:

1. The NA-200H is provided pre-assembled, sterile single use disposable.
2. The NA-200H includes a sterile single use disposable syringe for aspiration.

The comparison table provided shows all other similarities and differences to the legally marketed device. Please refer to Attachment 5 for details.

**VACLOK Syringe/ STOPCOCK**

The K12-MS2666 Syringe (VACLOK Syringe and Stopcock) is attached to the aspiration port on the handle section of the NA-200H. These devices will be provided sterile single use. We are offering these devices together to improve convenience to the customer. The syringe to be included in the package has been cleared by FDA as a cardiologist or radiologist during angiographic or radiologic, it is intended to be used for aspiration in this submission.

## D. Intended Use of the Device(s)

This instrument has been designed to be used with the ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

## E. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, Disposable Aspiration Needle NA-200H, VackLock Syringe and Stopcock does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2002

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K023272
Trade/Device Name: Disposable Aspiration Needle NA-200H
Regulation Number: 21 CFR §876.1076
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: September 30, 2002
Received: October 1, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): K023272

Device Name: DISPOSABLE ASPIRATION NEEDLE NA-200H

Indications for Use:

This instrument has been designed to be used with the ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023272